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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,995	03/23/2004	Marwan Abboud	21819-194U	2340
31292 7590 04/03/2007 CHRISTOPHER & WEISBERG, P.A. 200 EAST LAS OLAS BOULEVARD SUITE 2040 FORT LAUDERDALE, FL 33301			EXAMINER TOY, ALEX B	
			ART UNIT	PAPER NUMBER
			3739	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/03/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/806,995

Applicant(s)

ABBOUD ET AL.

Examiner

Alex B. Toy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,9-11 and 32-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,9-11,32-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

This Office Action is in response to applicant's amendment filed on February 12, 2007. All previous prior art rejections are maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 9-11, and 32-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding independent claims 1 and 11, the specification at no point discloses that "the pressure in the expandable membrane during ablation exceeds the target pressure, and is between approximately 3 to 20 psi" as claimed. This constitutes new matter unless applicant can clearly and specifically show evidence to the contrary in the written description as originally filed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 9, and 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Droegemueller (U.S. Pat. No. 3,294,628).

Regarding claim 1, Droegemueller discloses a method of inflating and deflating a catheter having an expandable membrane, the method comprising the steps of:

controllably inflating the expandable membrane 11 to at least target pressure;
ablating a desired tissue region, wherein the pressure in the expandable membrane during ablation exceeds the target pressure, and is between approximately 3 to 20 psi (Abstract, col. 3, ln. 58-62, and Fig. 6e); and
and controllably deflating the expandable membrane (col. 5, ln. 38-50 and col. 6, ln. 57-60):

Regarding claim 2, Droegemueller discloses the method of claim 1, further comprising keeping the expandable membrane 11 inflated until a region proximate the expandable membrane reaches a predetermined temperature range (col. 5, ln. 38-50 and col. 6, ln. 57-60).

Regarding claim 9, Droegemueller discloses the method of claim 1, wherein the step of ablating the desired tissue region is part of a cryoablation process (Abstract).

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Regarding claim 32, Droegemueller discloses the method of claim 1, wherein the step of controllably deflating the expandable membrane includes preventing deflation until a temperature in the balloon is higher than a predetermined temperature (col. 5, ln. 38-50 and col. 6, ln. 57-60).

Regarding claim 33, Droegemueller discloses the method of claim 1, wherein the step of controllably deflating the expandable membrane includes reducing adhesion between the expandable membrane and the desired tissue region (col. 5, ln. 38-50 and col. 6, ln. 57-60).

Regarding claim 34, see the preceding rejections of claims 1, 32, and 33.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3, 6, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Droegemueller ('628) in view of Yamaguchi (U.S. Pat. No. 5,433,740).

Regarding claims 3, Droegemueller discloses method of claim 1. The claim differs from Droegemueller in calling for the inflation/deflation control means to be located within a first console. Yamaguchi, however, teaches a control means 18 located within a first console 1 for inflating and deflating a balloon 6 (col. 4, ln. 47-64 and Figs. 1-2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have located the inflation/deflation control means of Droegemueller within a first console in view of the teaching of Yamaguchi as an obvious alternate means of better controlling the inflation and deflation of a balloon catheter that is known in the art.

Regarding claim 6, Droegemueller discloses method of claim 1. The claim differs from Droegemueller in calling for the method step of: if the target pressure is not reached, re-inflating the expandable membrane in order to reach the target pressure. Yamaguchi, however, teaches adjusting fluid flow in order to reach the target pressure in order to keep the balloon in intimate contact with the cavity wall and detect leaks (col. 4, ln. 54-61). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the step of claim 6 in the method of Droegemueller in view of the teaching of Yamaguchi in order to keep the balloon in intimate contact with the cavity wall and detect leaks.

Regarding claim 11, Droegemueller discloses a method for inflating and deflating a catheter having an expandable membrane, the catheter being part of a catheter

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system including a first console (see rejection of claim 3), a catheter, and an umbilical system coupling the first console to the catheter (see rejection of claim 3), the method comprising the steps of:

controllably inflating the expandable membrane proximate a desired tissue region, the expandable membrane being inflated to a target pressure in order to provide sufficient mechanical force against the desired tissue region;

ablating the desired tissue region, wherein the pressure in the expandable membrane during ablation exceeds the target pressure, and is between approximately 3 to 20 psi (Abstract, col. 3, ln. 58-62, and Fig. 6e); and

controllably deflating the expandable membrane (col. 5, ln. 38-50 and col. 6, ln. 57-60).

The claim differs from Droegemueller in calling for the method to further comprise evacuating air from the expandable membrane by creating a vacuum in the expandable membrane. Yamaguchi, however, teaches evacuating air from the expandable membrane by creating a vacuum in the expandable membrane (col. 6, ln. 47-52).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the step of evacuating air in the method of Droegemueller in view of the teaching of Yamaguchi in order to remove unwanted air from the balloon.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Droegemueller ('628) in view of Yamaguchi ('740) and further in view of Edwards (U.S. Pat. No. 6,258,087 B1).

Regarding claim 4, Droegemueller discloses the method of claims 1 and 3 in view of Yamaguchi. The claim differs from Droegemueller in view of Yamaguchi in calling for the inflation/deflation control means to be a Proportional Integral Derivative controller. Edwards, however, teaches a pump system that uses a Proportional Integral Derivative controller to control fluid flow (col. 36, ln. 15-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a Proportional Integral Derivative controller in the method of Droegemueller in view of Yamaguchi, further in view of the teaching of Edwards as an obvious means of better controlling fluid flow to the balloon that is known in the art.

Regarding claim 5, Droegemueller/Yamaguchi/Edwards disclose the method of claims 1, 3, and 4. In addition, the inflation/deflation control means of Yamaguchi includes a pressure switch 18 that controls an on/off valve (col. 4, ln. 62 – col. 5, ln. 3).

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Droegemueller ('628) in view of Stern (U.S. Pat. No. 5,443,470).

Regarding claim 10, Droegemueller discloses the method of claim 1. The claim differs from Droegemueller in calling for the step of ablating the desired tissue region to be part of a radio frequency ablation process. Stern, however, discloses an analogous inflatable device for ablating uterine tissue and further teaches that it is obvious and

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well-known in the art to use radio frequency and cryotherapy as obvious alternate energy sources for ablating uterine tissue. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used radio frequency energy instead of cryotherapy in the device of Droegemueller in view of the teaching of Stern that it is obvious and well-known in the art to use radio frequency and cryotherapy as obvious alternate energy sources for ablating uterine tissue.

Claims 3, 35, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Droegemueller ('628) in view of Joye (US PGPub 2002/0045894 A1).

Regarding claims 3, Droegemueller discloses method of claim 1. The claim differs from Droegemueller in calling for the inflation/deflation control means to be located within a first console. Joye, however, teaches a control means 68 located within a first console 78 in order to control the inflating and deflating of balloon 22 (pg. 6, ¶ 49 and Fig. 11). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have located the inflation/deflation control means of Droegemueller within a first console in view of the teaching of Joye as an obvious alternate means of better controlling the inflation and deflation of a balloon catheter that is known in the art.

Regarding claim 35, Droegemueller discloses the method of claims 1 and 3 in view of Joye. The claim differs from Droegemueller in calling for the inflation/deflation control means to be a proportional valve for controlling the delivery of fluid in order to reach and maintain a predetermined pressure in the balloon. Joye, however, teaches a

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control valve 68 for controlling the delivery of fluid in order to reach and maintain a predetermined pressure in the balloon (pg. 6, ¶ 49 and Fig. 11). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the inflation/deflation control means of Droegemueller be a valve for controlling the delivery of fluid in view of the teaching of Joye in order to reach and maintain a predetermined pressure in the balloon. Finally, applicant has not provided any criticality or unexpected result associated with using a proportional valve that defines over the system of Joye comprising a pressure transducer 23 coupled to a control valve 68 (pg. 6, ¶ 49 and Figs. 10-11).

Regarding claim 36, Droegemueller discloses the method of claims 1 and 3 in view of Joye. The claim differs from Droegemueller in calling for the inflation/deflation control means to be a fixed volume reservoir coupled to a shutoff valve located within the first console. Joye, however, teaches a inflation/deflation control means that is a fixed volume reservoir 72 coupled to a shutoff valve 68 located within the first console 78 (pg. 5, ¶ 47, pg. 6, ¶ 49, and Figs. 10-11). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the inflation/deflation control means of Droegemueller be a fixed volume reservoir coupled to a shutoff valve located within the first console in view of the teaching of Joye as an obvious alternate method of supplying and controlling fluid flow to a catheter balloon that is well-known in the art.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

Regarding independent claims 1 and 11, applicant argues that Droegmueller does not disclose that "the pressure in the expandable membrane during ablation exceeds the target pressure, and is between approximately 3 to 20 psi" as claimed.

First, applicant does not have written support for exceeding a target pressure or the specific pressure range.

Second, a target pressure can be any arbitrary pressure, so a pressure during inflation and prior to the final pressure is inherently a target pressure.

Third, applicant claims "between approximately 3 to 20 psi". The examiner maintains that "approximately" is a broad term that encompasses numbers reasonably below or above the range ends, such as 1, 2, 21, or 22 psi. Therefore, the examiner further maintains that Droegmueller's disclosure of "about 2 or 3 p.s.i." anticipates the claimed feature of having a pressure "between approximately 3 to 20 psi".

Fourth, Droegmueller discloses a pressure of "about 2 or 3 p.s.i.". Likewise, the examiner maintains that "about" is a broad term that encompasses numbers reasonably below or above the range ends, such as 4 or 5 psi, which also anticipate the claimed feature.

Finally, since applicant has no written support for this subject matter, there is no disclosure of criticality or unexpected result associated with the claimed pressure range that defines over the range of Droegmueller or that renders the range non-obvious to one of ordinary skill in the art.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AT *AT*
3/28/07

Michael Peffley
MICHAEL PEFFLEY
PRIMARY EXAMINER